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10/552,675	08/15/2006	Daniel Baumgartner	001227/0954	2286

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EXAMINER	
MERENE, JAN CHRISTOP L	
ART UNIT	PAPER NUMBER
3733	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,675	BAUMGARTNER ET AL.	
	Examiner	Art Unit	
	JAN CHRISTOPHER MERENE	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/5/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 16-17, 21, 24-26, 32** are rejected under 35 U.S.C. 102(b) as being anticipated by Rabbe et al US 5,776,198.

Regarding **Claim 16**, Rabbe et al discloses an intervertebral implant comprising (as seen in Fig 3): an intervertebral spacer body (#21) having at least an upper endface (#22) sized and configured to contact at least a portion of an upper vertebra; and at least one end member including a plurality of spikes (#120) for engaging at least a portion of the upper vertebra, wherein the at least one end member is slidably movable with respect to the intervertebral spacer body so that the at least one end member is moveable between a first position and a second position wherein when in the first position the plurality of spikes formed on the at least one end member extend beyond the upper endface of the spacer body and when in the second position the plurality of spikes formed on the at least one end member do not extend beyond the upper endface of the spacer body (see Col 5 lines 50-60, where a set screw #24 is used for fixing endplate #22 to the body #21, where the endplate #22 would be capable of being slidingly movable against #21 and where the spikes would extend/ not extend beyond

the body #21, depending where one would secure the set screw #24 or how far one would want to thread #22 against the body #21).

Regarding **Claim 17**, Rabbe et al discloses fastening means (#24) for securing the end member to the intervertebral spacer body in the first position.

Regarding **Claim 21**, Rabbe et al discloses at least one closing plate (#52) adjacent the upper endface.

Regarding **Claim 24**, Rabbe et al discloses a lower endface sized and configured to contact at least a portion of a lower vertebra; and the intervertebral implant further includes a second end member (#22) including a plurality of spikes for engaging at least a portion of the lower vertebra, wherein the second end member is also slidably movable with respect to the intervertebral spacer body so that the second end member is moveable between a first position and a second position wherein when in the first position the plurality of spikes (#120) formed on the second end member extend beyond the lower endface of the intervertebral spacer body and when in the second position the plurality of spikes formed on the second end member do not extend beyond the lower endface of the intervertebral spacer body (see Col 5 lines 50-60, where a set screw #24 is used for fixing endplate #22 to the body #21, where the endplate #22 would be capable of being slidingly movable against #21 and where the spikes would extend/ not extend beyond the body #21, depending where one would secure the set screw #24).

Regarding **Claim 25**, Rabbe et al discloses an intervertebral implant (as seen in Fig 3) comprising: an intervertebral spacer body (#21) having an upper endface (#22) sized and configured to contact at least a portion of an upper vertebra and a lower endface (#22) sized and configured to contact at least a portion of a lower vertebra; a first end member including a plurality of spikes (#120) for engaging at least a portion of the upper vertebra; and a second end member including a plurality of spikes (#120) for engaging at least a portion of the lower vertebra; wherein the first and second end members are slidably movable with respect to the intervertebral spacer body so that the first and second end members are moveable between a first position and a second position wherein when in the first position the plurality of spikes formed on the first end member extend beyond the upper endface of the spacer body and the plurality of spikes formed on the second end member extend beyond the lower endface of the spacer body, and when in the second position the plurality of spikes formed on the first end member do not extend beyond the upper endface and the plurality of spikes formed on the second end member do not extend beyond the lower endface (see Col 5 lines 50-60, where a set screw #24 is used for fixing endplate #22 to the body #21, where the endplate #22 would be capable of being slidingly movable against #21 and where the spikes would extend/ not extend beyond the body #21, depending where one would secure the set screw #24, or how far one would want to thread #22 against the body #21).

Regarding **Claim 26**, Rabbe et al discloses fastening means (#24) for securing the first and second end members to the intervertebral spacer body in the first position.

Regarding **Claim 31**, Rabbe et al discloses a method of implanting an intervertebral implant into an intervertebral disc space between upper and lower vertebrae, the method including the steps of:

providing an intervertebral implant (as seen in Fig 3) having an intervertebral spacer body having an upper endface and a lower endface (#22) for contacting the upper and lower vertebrae, respectively; and first and second end members, wherein the first and second end members are slidably disposed on the intervertebral spacer body, the first and second end members including a plurality of spikes (#120) formed on a surface thereof; inserting the intervertebral implant into the intervertebral disc; moving the first and second end members with respect to the intervertebral spacer body so that the plurality of spikes engage the upper and lower vertebrae, respectively; and securing the first and second end members with respect to the intervertebral spacer body (see Col 5 lines 50-60, where a set screw #24 is used for fixing endplate #22 to the body #21, where the endplate #22 would be capable of being slidingly movable against #21 and where the spikes would extend/ not extend beyond the body #21, depending where one would secure the set screw #24 or how far one would want to thread #22 against the body #21).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. **Claims 18-20, 22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rabbe et al US 5,776,198 and in view of Castro et al US 6,899,734.

Rabbe et al disclose the end member includes a top surface, a bottom surface, an internal bore defining an inner surface for slidably receiving the intervertebral spacer body therein (as seen in Fig 3), but does not specifically disclose one or more elastically deformable projections extending from the inner surface, the elastically deformable projections engaging the intervertebral spacer body when the end member is in the first position so that the position of the end member with respect to the spacer body is secured, wherein the one or more elastically deformable projections are hook-type members, the elastically deformable projections are integrally formed with the end member, wherein the intervertebral spacer body includes one or more recesses for engaging the one or more elastically deformable projections

However, Castro et al discloses a similar device (as seen in Fig 3a) with an end member (#40) includes a top surface, a bottom surface, an internal bore (as seen in Fig 3a) and one or more elastically deformable projections (#48) extending from the inner surface, the elastically deformable projections engaging the intervertebral spacer body when the end member is in the first position so that the position of the end member with respect to the spacer body is secured, wherein the one or more elastically deformable projections are hook-type members, the elastically deformable projections are integrally formed with the end member, wherein the intervertebral spacer body (#12) includes one or more recesses (#23 as seen in Fig 1) for engaging the one or more elastically deformable projections (see Fig 1 and Fig 3a and Col 4 lines 45-53, which disclose

hook type members, semi-resilient detents #48, which can easily be snapped into recess #23).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Rabbe et al to include the deformable projections (#48) and the recess (#23) of Castro et al, as disclosed above because the deformable projections (detents #48) with a corresponding recess is a simple substitution of one known element, known in the art, for another to secure an end plate onto an intervertebral spacer and is an easy way for a surgeon to simply "snap" the endplate into place (see Col 4 lines 45-53). (The examiner also notes that the holes (#28) of Rabbe et al would also be capable of locking in deformable projections (#48) of Castro et al, if one would so choose to and properly size the projections).

7. **Claim 21** is rejected under 35 U.S.C. 103(a) as being unpatentable over Rabbe et al US 5,776,198 and Castro et al US 6,899,734, as applied to Claim 18 above, in further view of Fortier US 6,106,539.

Rabbe et al and Castro et al disclose the claimed invention with a deformable projection, as recited above, but does not specifically disclose the spacer body includes a shoulder for engaging one or more elastically deformable projections.

However Fortier discloses a similar deformable projection (#28c as seen in Fig 7) with a shoulder (#34c)on the body to which it is connecting to.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the spacer of Rabbe et al to include a shoulder (#34c) as

taught by Fortier because a shoulder provides a stop means for a detent mechanism (see Col 2 lines 37-39).

8. **Claims 27-29, 31** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rabbe et al US 5,776,198 and in view of Castro et al US 6,899,734.

Rabbe et al disclose the end member includes a top surface, a bottom surface, an internal bore defining an inner surface for slidably receiving the intervertebral spacer body therein (as seen in Fig 3), but does not specifically disclose one or more elastically deformable projections extending from the inner surface, the elastically deformable projections engaging the intervertebral spacer body when the end member is in the first position so that the position of the end member with respect to the spacer body is secured, wherein the one or more elastically deformable projections are hook-type members, the elastically deformable projections are integrally formed with the end member, wherein the intervertebral spacer body includes one or more recesses for engaging the one or more elastically deformable projections

However, Castro et al discloses a similar device (as seen in Fig 3a) with an end member (#40) includes a top surface, a bottom surface, an internal bore (as seen in Fig 3a) and one or more elastically deformable projections (#48) extending from the inner surface, the elastically deformable projections engaging the intervertebral spacer body when the end member is in the first position so that the position of the end member with respect to the spacer body is secured, wherein the one or more elastically deformable

projections are hook-type members, the elastically deformable projections are integrally formed with the end member, wherein the intervertebral spacer body (#12) includes one or more recesses (#23 as seen in Fig 1) for engaging the one or more elastically deformable projections (see Fig 1 and Fig 3a and Col 4 lines 45-53, which disclose hook type members, semi-resilient detents #48, which can easily be snapped into recess #23).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Rabbe et al to include the deformable projections (#48) and the recess (#23) of Castro et al, as disclosed above because the deformable projections (detents #48) with a corresponding recess is a simple substitution of one known element, known in the art, for another to secure an end plate onto an intervertebral spacer and is an easy way for a surgeon to simply "snap" the endplate into place (see Col 4 lines 45-53). (The examiner also notes that the holes (#28) of Rabbe et al would also be capable of locking in deformable projections (#48) of Castro et al, if one would so choose to and properly size the projections).

9. **Claim 30** is rejected under 35 U.S.C. 103(a) as being unpatentable over Rabbe et al US 5,776,198 and Castro et al US 6,899,734, as applied to Claim 27 above, in further view of Fortier US 6,106,539.

Rabbe et al and Castro et al disclose the claimed invention with a deformable projection, as recited above, but does not specifically disclose the spacer body includes a shoulder for engaging one or more elastically deformable projections.

However Fortier discloses a similar deformable projection (#28c as seen in Fig 7) with a shoulder (#34c)on the body to which it is connecting to.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the spacer of Rabbe et al to include a shoulder (#34c) as taught by Fortier because a shoulder provides a stop means for a detent mechanism (see Col 2 lines 37-39).

Response to Arguments

10. Applicant's arguments with respect to claims 1-5 have been considered but are moot in view of the new ground(s) of rejection (see above).

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

The prior art made of record and relied upon is considered pertinent to the applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAN CHRISTOPHER MERENE whose telephone number is (571)270-5032. The examiner can normally be reached on 8 am - 6pm Mon-Thurs, alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jan Christopher Merene/
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733